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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,674	07/14/2006	Marcel Wijlaars	0470-060131	1707

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EXAMINER	
HELM, CARALYNNE E	
ART UNIT	PAPER NUMBER
1615	
MAIL DATE	DELIVERY MODE
03/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,674	WIJLAARS ET AL.	
	Examiner	Art Unit	
	CARALYNNE HELM	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/29/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Note to Applicant: References to paragraphs in non-patent literature refers to full paragraphs (e.g. 'page 1 column 1 paragraph 1' refers to the first full paragraph on page 1 in column 1 of the reference)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the limitation "said methacrylate" in line 2. There is insufficient antecedent basis for this limitation in the claim. Further the claim also recites that only a portion of the "said methacrylate" is composed of methacrylate, which also renders the indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The four factual inquiries of Graham v. Deere Co. have been fully considered and analyzed in the rejections that follow.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8-9 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. (Artificial Organs 2000 24:174-178) in view of Pissis et al. (Proceedings of the 10th International Symposium on Electrets 1999 p561-564).

Malmonge et al. teach a copolymer of 2-hydroxyethyl methacrylate (HEMA) and acrylic acid (AA) as artificial articular cartilage in a joint prosthesis (see page 175 column 1 paragraph 2-3; instant claims 8, 9, and 14). They go on to teach that the hydrogels made of this material have negative (ionized) groups fixed within the macromolecular network that are believed to participate in compressive strength of the material (see page 174 column 2 paragraph 1 line15-page 175 column 1 line 5 and page 175 column 1 paragraphs 2-3; instant claim 8). Ionized groups were therefore added to the hydrogel prior to polymerization and were present after polymerization (see page 176 column 1 paragraph 1; instant claim 8). Malmonge et al. also

teach the ratio of HEMA to AA in the polymer to be 97.5 to 2.5 as well as 95 to 5 (see page 175 column 1 paragraph 4; instant claim 8). Malmonge et al. do not teach whether this ratio is based upon mass or moles. In the case where the ratio described the molar balance, the corresponding mass percentage of AA in the polymer would be 1.8% (mass percentage corresponding to 2.5 mol%) and 3.6% (mass percentage corresponding to 5 mol%), as calculated by the examiner. Further, Malmonge et al. also teach the hydrogel being soaked (saturated) in a liquid solution (see figure 1 and caption; instant claim 12). Although Malmonge et al. do not teach the incorporation of fibers into the taught hydrogel, Pissis et al. teach the incorporation of Nylon particles (fibers), a swellable polyurethane, into a hydrogel (see page 561 paragraph 1; instant claims 8 and 13). Pissis et al. also teach that all polymer hydrogels would benefit from having their mechanical properties improved and that the inclusion of the Nylon serves this purpose (see page 561 paragraph 1; instant claims 8 and 13). Further Pissis et al. teach the inclusion of the Nylon particles at 10% (see page 561 paragraph 2 lines 17-18; instant claims 8 and 13). It therefore would have been obvious to one of ordinary skill in the art at the time of the invention was made to use the teachings of Malmonge et al. in view of Pissis et al. to produce a HEMA-AA hydrogel with 10% Nylon fibers (dry weight), such that the AA content was from 1-5% (dry weight). Consequently, the saturation of the Pissis et al. modified gel of Malmonge et al. would also have the swellable Nylon fibers saturated as well (see figure 1 and caption; instant claim 12). Therefore claims 8-9 and 12-14 are obvious over Malmonge et al. in view of Pissis et al.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Malmonge et al. in view of Pissis et al. and Kou et al. (Journal of Controlled Release 1990 12:241-250).

The teachings of Malmonge et al. in view of Pissis et al. make obvious a HEMA-AA hydrogel with 10% Nylon fibers (dry weight), such that the AA content was from 1-5% (dry weight). However, this modified reference does not teach the use of methacrylic acid (MA) in the hydrogel. Kou et al. teach a HEMA-MA hydrogel as being known in the art at the time of invention (see page 241 column 1 paragraph 1; instant claims 8 and 10). Further, the MA only differs from the AA in that it has an additional methyl group in the place one hydrogen. Thus in a hydrogel HEMA-MA would have negative groups fixed within its macromolecular network like HEMA-AA. Therefore since it would be obvious for one of ordinary skill in the art to pursue known options within their technical grasp, it would have been obvious to use HEMA-MA instead of HEMA-AA in the Pissis et al. modified hydrogel of Malmonge et al. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to use the monomer ratios taught by Malmonge et al. where MA replaces AA. Therefore claims 8 and 10 are obvious over Malmonge et al. in view of Pissis et al. and Kou et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Michael P Woodward/
Supervisory Patent Examiner, Art Unit 1615